



Practitioner's Docket No. 10729794

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Anderson, David R., Emily J. Reinhard, Stephen A. Kolodziej, William F. Vernier, and Shridhar G. Hegde

Application No.: 10/729,794

Group No.: 1625

Filed: December 5, 2003

Examiner: Charanjit S. Aulakh

For: METHOD OF MAKING TRICYCLIC AMINOCYANOPYRIDINE COMPOUNDS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
BEFORE MAILING DATE OF EITHER A FINAL ACTION
OR NOTICE OF ALLOWANCE (37 C.F.R. § 1.97(c))

TIME OF TRANSMITTAL OF ACCOMPANYING
INFORMATION DISCLOSURE STATEMENT

1. The information disclosure statement transmitted herewith is being filed *after* three months of the filing date of this national application or the date of entry of the national stage as set forth in Section 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but *before* the mailing date of either

- (1) a final action under § 1.113 or
(2) a notice of allowance under § 1.311

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10*

(When using Express Mail, the Express Mail label number is *mandatory*;
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I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. § 1.8(a)

☒ with sufficient postage as first class mail.

37 C.F.R. § 1.10*

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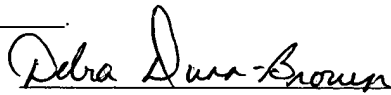
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TRANSMISSION

☐ facsimile transmitted to the Patent and Trademark Office, (703) _____

07/02/2004 BABRAHA1 00000020 10729794

01 FC:1806 Date: 6/28/04 180.00 OP


Signature

Debra Dunn-Brown

(type or print name of person certifying)

* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

whichever occurs first.

FEE

2. Accompanying this transmittal is the fee for submission of an information disclosure statement under section 1.97(c). (\$180.00)

FEE PAYMENT

3. Applicant elects the option to pay the fee set forth in 37 C.F.R. § 1.17(p) for submission of an information disclosure statement under § 1.97(c) (\$180.00).

Fee due \$180.00

METHOD OF PAYMENT OF FEE

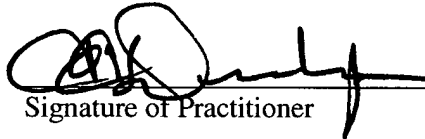
4. Attached is Check No. 24746 in the amount of \$180.00.

Charge any additional fees required by this paper or credit any overpayment to Account No. 50-2548.

A duplicate of this paper is attached.

Date:

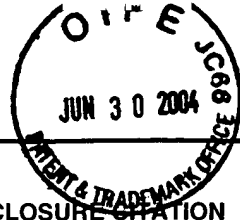
June 28, 2004



Signature of Practitioner

Reg. No.: 35,124
Tel. No.: 864-250-2238

Charles E. Dunlap
Nelson Mullins Riley & Scarborough, LLP
1320 Main Street - 17th Floor
Columbia, SC 29201



| | | |
|--|---------------------------------------|----------------------------------|
| Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i> | Docket Number Optional 18438/09040 | Application Number 10/729,794 |
| | Applicant Anderson, et al. | Filing Date December 5, 2003 |
| | Examiner Unknown | Group Art Unit Unknown |

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|---------------------|-----------------|----------|------------------|-------|----------|-------------------------------|
| | 6 4 3 2 9 6 2 | 08/13/02 | Horneman | 514 | 255.06 | |
| | 6 3 3 5 3 4 0 | 01/01/02 | Gallagher et al. | 514 | 252.05 | |
| | 6 2 6 8 1 6 3 | 07/31/01 | Kongsbak et al | 435 | 15 | |
| | 6 2 1 8 1 3 6 | 04/17/01 | Kumar et al. | 435 | 15 | |
| | 6 0 4 6 2 0 8 | 04/04/00 | Adams et al | 514 | 274 | |

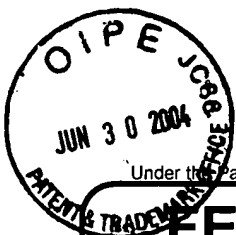
FOREIGN PATENT DOCUMENTS

| | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | Translation | |
|--|-----------------|----------|--------------------------|-------|----------|-------------|----|
| | | | | | | YES | NO |
| | WO 99/51735 | 14.10.99 | Alexey Kotlyarov, et al. | C12N | 15/11 | | X |
| | WO 01/29037 A2 | 26.04.01 | Barry L. Johnson, et al. | C07D | 471/00 | X | |
| | WO 01/47892 A1 | 05.07.01 | Dan M. Berger, et al. | C07D | 215/54 | X | |

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

| | |
|--|--|
| | United States Patent Application Publication, Pub. No. US 2001/051620 A1, December 13, 2001 |
| | Article from Bioorganic & Medicinal Chemistry Letters, Vol. 5, No. 23, pp. 2783-2788, 1995 by C. W. Smith et al., entitled The Anti-Rheumatic Potential of a Series of 2,4-Di-substituted-4H-Naphtho[1,2-b]Pyran-3-Carbonitriles. |
| | Abstract No. 132:260099 entitled "Anti-Inflammatory Substances" by N. Hirasawa et al., <i>Tanpakushitsu Kakusan Koso</i> , 45(6): 1199-1203 (2000) |
| | Abstract from J. Biol Chem., 2003 Jan., Vol. 278(3), pp. 1450-1456 by J.R. Burke et al. entitled BMS-34551 is a highly selective inhibitor of I kappa B kinase that binds at an allosteric site of the enzyme and blocks NF-kappa B-dependent transcription in mice. |
| | Abstract from The Journal of Biochemical Chemistry, 2002 Oct., Vol. 367(Pt 2): pp. 525-532 by A. Knebel, et al. entitled Stress-induced regulation of eukaryotic elongation factor 2 kinase by SB 203580-sensitive and -insensitive pathways. |
| | Abstract from Biochim Biophys. Acts., 2002 July, Vol. 1598(1-2): pp. 88-97 by J.F. Schindler et al. entitled Examination of the kinetic mechanism of mitogen-activated protein kinase activated protein kinase-2. |
| | Article from FEBS Letters 392 (1996), pp. 209-214 by A. Clifton et al. entitled A comparison of the substrate specificity of MAPKAP kinase-2 and MAPKAP kinase-3 and their activation by cytokines and cellular stress. |
| | Article from FEBS Letters 364 (1995), pp. 229-233 by A. Cuenda et al. entitled SB 203580 is a specific inhibitor of a MAP kinase homologue which is stimulated by cellular stresses and interleukin-1. |
| | Article from The Journal of Immunology, 2000 July, 165: pp. 3951-3958, by A. K. De et al. entitled Exaggerated Human Monocyte IL-10 Concomitant to Minimal TNF- α Induction by Heat-Schock Protein 27 (Hsp27) Suggests Hsp27 is Primarily an Antiinflammatory Stimulus. |
| | Article from The American Society for Biochemistry and Molecular Biology, Inc., 1995 Nov., Vol.:270(45), pp. 27213-27221 by K. Engel et al. entitled Constitutive Activation of Mitogen-activated Protein Kinase-activated Protein Kinase 2 by Mutation of Phosphorylation Sites and an A-helix Motif(*) |
| | Article from The Journal of Biological Chemistry, 1997 Feb., Vol. 272(6): pp. 3296-3301 by I. N. Foltz et al. entitled Hemopoietic Growth Factors with the Exception of Interleukin-4 Activate the p38 Mitogen-activated Protein Kinase Pathway. |
| | Article from Biochemical Journal, 1995 Sept., 311(Pt. 3): pp. 735-738 by G. W. Gould et al. entitled The activation of distinct mitogen-activated protein kinase cascades is required for the stimulation of 2-deoxyglucose uptake by interleukin-1 and insulin-like growth factor-1 in KB cells. |

| | | | |
|--|--|---------------------------------------|----------------------------------|
| Form PTO-1449 | | Docket Number Optional 18438/09040 | Application Number 10/729,794 |
| INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i> | | Applicant Anderson, et al. | Filing Date December 5, 2003 |
| | | Examiner Unknown | Group Art Unit Unknown |
| | Article from The Journal of Immunology, 2001 July, 167: pp. 3953-3961 by M. O. Hannigan et al. entitled Abnormal Migration Phenotype of Mitogen-Activated Protein Kinase-Activated Protein Kinase 2 ^{-/-} Neutrophils in Zigmond Chambers Containing Formyl-Methionyl-Leucyl-Phenylalanine Gradients. | | |
| | Article from The Journal of Biological Chemistry, 1999 May, Vol. 274(20): pp. 14434-14443 by O. Heidenreich et al. entitled MAPKAP Kinase 2 Phosphorylates Serum Response Factor in Vitro and in Vivo*. | | |
| | Article from The Journal of Biological Chemistry, 2001 July, Vol. 276(45): pp. 41856-41861 by R. Janknecht entitled Cell Type-specific Inhibition of the ETS Transcription Factor ER81 by Mitogen-activated Protein Kinase-activated Protein Kinase 2*. | | |
| | Article from Biochemical Society Transactions, 2002, Vol. 30(6): pp. 959-963 by A. Kotlyarov et al. entitled Is MK2 (mitogen-activated protein kinase-activated protein kinase 2) the key for understanding post-transcriptional regulation of gene expression? | | |
| | Article from Nature Cell Biology 1999 June, Vol. 1: pp. 94-97 by A. Kotlyarov et al. entitled MAPKAP kinase 2 is essential for LPS-induced TNF- α biosynthesis. | | |
| | Article from The Journal of Immunology, 2002 March, Vol. 168(9): pp. 4667-4673 by M. D. Lehner et al. entitled Mitogen-Activated Protein Kinase-Activated Protein Kinase 2-Deficient Mice Show Increased Susceptibility to <i>Listeria monocytogenes</i> Infection. | | |
| | Article from Molecular Endocrinology, 2001, Vol. 15(5): pp. 716-733 by E. T. Maizels et al. entitled Developmental Regulation of Mitogen-Activated Protein Kinase-Activated Kinases-2 and -3 (MAPKAPK-2/-3) in Vivo during Corpus Luteum Formation in the Rat. | | |
| | Article from The Journal of Biochemical Chemistry, 1998 Sept., Vol. 273(38): pp. 24832-24838 by K. Miyazawa et al entitled Regulation of Interleukin-1 β -induced Interleukin-6 Gene Expression in Human Fibroblast-like Synoviocytes by p38 Mitogen-activated Protein Kinase. | | |
| | Article from Circulation Research, 2000 Feb.: pp. 144-151 by N. Nakano et al. entitled Ischemic Preconditioning Activates MAPKAPK2 in the Isolated Rabbit Heart. | | |
| | Article from The Journal of Neuroscience, 1998 March, Vol. 18(5): pp. 1633-1641 by N. Bhat et al. entitled Extracellular Signal-Regulated Kinase and p38 Subgroups of Mitogen-Activated Protein Kinases Regulate Inducible Nitric Oxide Synthase and Tumor Necrosis Factor- α Gene Expression in Endotoxin-Stimulated Primary Glial Cultures. | | |
| | Article from The Journal of Biological Chemistry, 2002 Feb., Vol. 277(5): pp. 3065-3068 by A. Neiningner et al. entitled MK2 Targets AU-rich Elements and Regulates Biosynthesis of Tumor Necrosis Factor and Interleukin-6 Independently at Different Post-transcriptional Levels*. | | |
| | Article from The Journal of Biological Chemistry, 2000 April, Vol. 275(15): pp. 11284-11290 by E. Paine et al. entitled Arachidonic Acid Activates Mitogen-activated Protein (MAP) Kinase-activated Protein Kinase 2 and Mediates Adhesion of a Human Breast Carcinoma Cell Line to Collagen Type IV through a p38 MAP Kinase-dependent Pathway. | | |
| | Article from Blood, 1999 Jan., Vol. 93(1): pp. 217-225 by M. P. Scheid et al. entitled Ceramide and Cyclic Adenosine Monophosphate (cAMP) Induce cAMP Response Element Binding Protein Phosphorylation via Distinct Signaling Pathways While Having Opposite Effects on Myeloid Cell Survival. | | |
| | Article from Proc. Natl. Acad. Sci, 2000 May, Vol. 97(10): pp. 5261-5266 by O. Werz et al. entitled 5-Lipoxygenase is phosphorylated by p38 kinase-dependent MAPKAP kinases. | | |
| | Article from Kidney International, 2001 March, Vol. 60: pp. 858-871 by W. A. Wilmer et al. entitled Chronic exposure of human mesangial cells to high glucose environments activates the p38 MAPK pathway. | | |
| EXAMINER | | DATE CONSIDERED | |
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant. | | | |



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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 180.00

Complete if Known

| | |
|----------------------|---------------------|
| Application Number | 10/729,794 |
| Filing Date | December 5, 2003 |
| First Named Inventor | Anderson et al. |
| Examiner Name | Charanjit S. Aulakh |
| Art Unit | 1625 |
| Attorney Docket No. | 18438/09040 |

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit
Account
Number
Deposit
Account
Name

50-2548

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

| Large Entity Fee Code (\$) | Small Entity Fee Code (\$) | Fee Description | Fee Paid |
|-------------------------------|-------------------------------|------------------------|------------|
| 1001 770 | 2001 385 | Utility filing fee | |
| 1002 340 | 2002 170 | Design filing fee | |
| 1003 530 | 2003 265 | Plant filing fee | |
| 1004 770 | 2004 385 | Reissue filing fee | |
| 1005 160 | 2005 80 | Provisional filing fee | |
| SUBTOTAL (1) | | | (\$) 0.00 |

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims - 20** = X =
Independent Claims - 3** = X =
Multiple Dependent =

| Large Entity Fee Code (\$) | Small Entity Fee Code (\$) | Fee Description | Fee Paid |
|-------------------------------|-------------------------------|--|------------|
| 1202 18 | 2202 9 | Claims in excess of 20 | |
| 1201 86 | 2201 43 | Independent claims in excess of 3 | |
| 1203 290 | 2203 145 | Multiple dependent claim, if not paid | |
| 1204 86 | 2204 43 | ** Reissue independent claims over original patent | |
| 1205 18 | 2205 9 | ** Reissue claims in excess of 20 and over original patent | |
| SUBTOTAL (2) | | | (\$) 0.00 |

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

| Large Entity Fee Code (\$) | Small Entity Fee Code (\$) | Fee Description | Fee Paid |
|-------------------------------|-------------------------------|--|----------|
| 1051 130 | 2051 65 | Surcharge - late filing fee or oath | |
| 1052 50 | 2052 25 | Surcharge - late provisional filing fee or cover sheet | |
| 1053 130 | 1053 130 | Non-English specification | |
| 1812 2,520 | 1812 2,520 | For filing a request for ex parte reexamination | |
| 1804 920* | 1804 920* | Requesting publication of SIR prior to Examiner action | |
| 1805 1,840* | 1805 1,840* | Requesting publication of SIR after Examiner action | |
| 1251 110 | 2251 55 | Extension for reply within first month | |
| 1252 420 | 2252 210 | Extension for reply within second month | |
| 1253 950 | 2253 475 | Extension for reply within third month | |
| 1254 1,480 | 2254 740 | Extension for reply within fourth month | |
| 1255 2,010 | 2255 1,005 | Extension for reply within fifth month | |
| 1401 330 | 2401 165 | Notice of Appeal | |
| 1402 330 | 2402 165 | Filing a brief in support of an appeal | |
| 1403 290 | 2403 145 | Request for oral hearing | |
| 1451 1,510 | 1451 1,510 | Petition to institute a public use proceeding | |
| 1452 110 | 2452 55 | Petition to revive - unavoidable | |
| 1453 1,330 | 2453 665 | Petition to revive - unintentional | |
| 1501 1,330 | 2501 665 | Utility issue fee (or reissue) | |
| 1502 480 | 2502 240 | Design issue fee | |
| 1503 640 | 2503 320 | Plant issue fee | |
| 1460 130 | 1460 130 | Petitions to the Commissioner | |
| 1807 50 | 1807 50 | Processing fee under 37 CFR 1.17(q) | |
| 1806 180 | 1806 180 | Submission of Information Disclosure Stmt | 180 |
| 8021 40 | 8021 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 770 | 2809 385 | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 770 | 2810 385 | For each additional invention to be examined (37 CFR 1.129(b)) | |
| 1801 770 | 2801 385 | Request for Continued Examination (RCE) | |
| 1802 900 | 1802 900 | Request for expedited examination of a design application | |

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 180.00

SUBMITTED BY

(Complete if applicable)

| | | | | | |
|-------------------|-------------------|-----------------------------------|---------------|-----------|--------------|
| Name (Print/Type) | Charles E. Dunlap | Registration No. (Attorney/Agent) | 35,124 | Telephone | 864-250-2238 |
| Signature | | Date | June 28, 2004 | | |

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This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.
SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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